

# ASSEMBLY, No. 3260

## STATE OF NEW JERSEY 218th LEGISLATURE

INTRODUCED FEBRUARY 12, 2018

**Sponsored by:**

**Assemblywoman VALERIE VAINIERI HUTTLE**

**District 37 (Bergen)**

**SYNOPSIS**

“Reproductive Donation Safety Act.”

**CURRENT VERSION OF TEXT**

As introduced.



1 AN ACT concerning the regulation of semen banks and  
2 supplementing Title 26 of the Revised Statutes and Title 2C of  
3 the New Jersey Statutes.

4  
5 **BE IT ENACTED** *by the Senate and General Assembly of the State*  
6 *of New Jersey:*

7  
8 1. This act shall be known and may be cited as the  
9 “Reproductive Donation Safety Act.”

10  
11 2. As used in this act:

12 “Assisted reproductive technology” means clinical treatments  
13 and laboratory procedures that are performed with the intent of  
14 establishing a pregnancy.

15 “Collection” means the obtaining of semen from donors.

16 “Commissioner” means the Commissioner of Health.

17 “Department” means the Department of Health.

18 “Distribution” means the removal of semen from a semen bank  
19 to any other location for processing or storage or for the purpose of  
20 providing the semen for reproductive or research purposes.

21 “Donor” means an individual who donates semen from that  
22 individual to a semen bank for use in assisted reproductive  
23 technology procedures.

24 “Federal regulations” means regulations adopted by the federal  
25 Food and Drug Administration as set forth at 21 CFR Part 1271  
26 governing human reproductive tissue banks and any other federal  
27 regulations that may apply to the operation of semen banks.

28 “Licensee” means a person holding a license under the  
29 provisions of this act.

30 “Person” means a natural person or a partnership, association,  
31 corporation, institution, agency, or other similar type of entity.

32 “Processing” means the technical stages required to prepare and  
33 identify semen as to its suitability.

34 “Registry” means the New Jersey Semen Donor Registry  
35 established pursuant to section 6 of this act.

36 “Semen bank” means a commercial or noncommercial activity  
37 involving the handling of human semen that participates in the  
38 collection, processing, storage, or distribution of semen for use in  
39 assisted reproductive technology procedures.

40 “Storage” means the holding of semen in connection with  
41 collection or processing prior to distribution.

42  
43 3. a. A person shall not operate or conduct a semen bank in  
44 this State unless licensed by the commissioner under the provisions  
45 of this act. The license required by this act shall be in addition to  
46 any other license or permit required by a local board of health or  
47 other body exercising the powers of such a board in a municipality  
48 in this State.

1       b. The commissioner shall not license a person to operate or  
2       conduct a semen bank pursuant to this act unless the commissioner  
3       is satisfied that the applicant for licensure has demonstrated good  
4       character, competency, and integrity, and the applicant shall furnish  
5       such information to the commissioner as the commissioner may  
6       require for this purpose.

7       c. A license issued pursuant to this section shall expire on  
8       December 31 of each calendar year, and application for renewal  
9       therefor shall be made on or before November 10 on forms provided  
10      by the department. A fee necessary to conduct semen bank  
11      licensure operations, as provided in subsection d. of this section,  
12      shall accompany the original application for a license and each  
13      renewal thereof. The licensee shall conspicuously display the  
14      original or a certified copy of the license at the premises occupied  
15      as a semen bank.

16      d. (1) The commissioner shall charge a fee for each license or  
17      renewal thereof in an amount determined by the commissioner to be  
18      reasonably necessary to cover the cost to the department of carrying  
19      out the provisions of this act, but the fee may vary based on the  
20      number of collections made by a facility.

21      (2) The commissioner may, pursuant to the "Administrative  
22      Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), periodically  
23      increase the fees to reflect increased State costs in semen bank  
24      licensure operations.

25      e. The income received from licensure and renewal fees  
26      pursuant to this section shall be appropriated to the department to  
27      effectuate the purposes of this act.

28      f. A license shall be issued to any person who has been  
29      conducting a semen bank prior to the effective date of this act upon  
30      submission of a properly completed application on a form and in a  
31      manner prescribed by the commissioner, including documentation  
32      to the satisfaction of the commissioner that the semen bank is  
33      accredited by the American Association of Tissue Banks and is in  
34      compliance with federal regulations, and payment of the application  
35      fee. The license shall be renewable as provided in this act and shall  
36      be subject to all the provisions of this act.

37      g. (1) A license issued in accordance with the provisions of  
38      this act may be suspended or revoked by the commissioner for a  
39      violation of any of the provisions of this act or any rules or  
40      regulations adopted pursuant thereto.

41      (2) (a) The commissioner, before refusing to grant a license, or  
42      before suspending or revoking a license previously granted, except  
43      as hereinafter provided in this act, shall give notice to the applicant  
44      or licensee personally, or by mail addressed to that person at the  
45      person's last known address, and shall afford that person an  
46      opportunity to be heard with respect thereto at a time and place  
47      specified in the notice. The applicant or licensee shall have the

1 right to be heard in person or by an attorney, and to offer evidence  
2 pertinent to the subject of the hearing.

3 (b) A duly certified copy of the order of the commissioner  
4 issued as a result of the hearing shall be served on the applicant or  
5 the licensee personally, or by mail addressed to that person at the  
6 person's last known address.

7 (c) If the applicant or licensee is a corporation, the notice issued  
8 pursuant to subparagraph (a), and the order issued pursuant to  
9 subparagraph (b), of this paragraph shall be served in the same  
10 manner upon an officer or registered agent of the corporation.

11

12 4. a. A licensee shall not collect semen without having first  
13 obtained the following from the prospective donor, on a form and in  
14 a manner prescribed by the commissioner:

15 (1) a completed registration statement which shall set forth the  
16 name and address of the donor and shall contain such other  
17 information as prescribed by regulation of the commissioner or  
18 required pursuant to federal regulations; and

19 (2) a donor information sharing statement as set forth in section  
20 5 of this act.

21 b. (1) The commissioner shall establish by regulation  
22 standards of operation for semen banks, including standards for the  
23 collection, processing, storage, and distribution of semen, in  
24 consultation with the American Association of Tissue Banks and  
25 the American Society for Reproductive Medicine, and may  
26 incorporate in the regulations by reference the requirements or  
27 guidelines adopted by those entities, as well as federal regulations.

28 (2) The regulations shall include, but not be limited to,  
29 provision for:

30 (a) qualifications for personnel employed in a semen bank;

31 (b) restrictions upon the use of semen donors;

32 (c) standards for collection, processing, storage, and distribution  
33 of semen; and

34 (d) evaluation of the performance of semen banks.

35 c. (1) The commissioner shall impose a limit on semen  
36 donations by an individual donor in accordance with the  
37 recommendations of the American Society for Reproductive  
38 Medicine.

39 (2) A semen bank shall report the information contained in the  
40 completed registration statement that it obtains for each donor to the  
41 New Jersey Semen Donor Registry established pursuant to section 6  
42 of this act, and shall check with the registry prior to obtaining each  
43 donation of semen from any donor, as prescribed by regulation of  
44 the commissioner for the purposes of paragraph (1) of this  
45 subsection.

46

47 5. a. (1) The donor information sharing statement, required  
48 pursuant to section 4 of this act, shall specify the level of

1 information that shall be shared with an individual 18 years of age  
2 or older if that individual submits a written, notarized request to  
3 obtain information pursuant to subsection d. of this section.

4 (2) The donor may, in the future, ask to update and submit a  
5 revised statement to the semen bank, which shall report this  
6 information to the New Jersey Semen Donor Registry.

7 b. The donor information sharing statement shall specify the  
8 following options, from which the donor may select one:

9 (1) "Complete information sharing" means a donor consents to  
10 the release of the donor's name, last known address, and telephone  
11 number, if available;

12 (2) "Intermediary information sharing only" means a donor does  
13 not consent to the release of the information set forth in paragraph  
14 (1) of this subsection, but agrees to communication with the  
15 individual requesting the information through a third party  
16 designated by the donor on the original or revised statement;

17 (3) "Medical information sharing only" means a donor does not  
18 consent to the release of the information set forth in paragraph (1)  
19 of this subsection, but agrees to periodic communication limited to  
20 the sharing of non-identifying family medical history information,  
21 with the individual requesting the information through a third party  
22 designated by the donor on the original or revised statement.

23 c. The licensee shall maintain a copy of the completed and any  
24 revised donor information sharing statement.

25 d. (1) An individual who is 18 years of age or older may submit  
26 to the registry a written, notarized request for information about the  
27 person whom the individual has reason to believe was a donor.

28 (2) If the donor submitted a donor information sharing statement  
29 specifying "complete information sharing," the registry shall  
30 provide that donor information to the requester.

31 (3) If the donor submitted a donor information sharing statement  
32 specifying "intermediary information sharing only," the registry  
33 shall inform the requester of the donor's wish to communicate with  
34 the requester through the third party designated by the donor on the  
35 donor information sharing statement.

36 (4) If the donor submitted a donor information sharing statement  
37 specifying "medical information sharing only," the registry shall  
38 inform the requester of the donor's wish for periodic  
39 communication limited to the sharing of non-identifying family  
40 medical history information with the requester through a third party  
41 designated by the donor on the donor information sharing statement.

42 (5) If the donor submits a revised statement to the semen bank  
43 that is reported to the registry pursuant to paragraph (2) of  
44 subsection a. of this section, the registry shall share information  
45 with the requester based on the revised statement in accordance  
46 with the provisions of this section.

- 1       6. a. The commissioner shall establish and operate a Statewide  
2 registry, to be designated as the New Jersey Semen Donor Registry,  
3 which shall be the repository for information obtained from semen  
4 banks pursuant to sections 4 and 5 of this act.
- 5       b. The commissioner shall adopt regulations for the  
6 implementation, operation, and evaluation of the registry, including,  
7 but not limited to, regulations that prescribe the manner for a semen  
8 bank to submit information to, and for a semen bank or an  
9 individual to obtain information from, the registry, and establish  
10 procedures to ensure the accuracy and confidentiality of  
11 information submitted to the registry.
- 12       c. The commissioner may contract with a public or private  
13 entity to implement or operate the registry.
- 14       d. All information collected or developed by the registry that  
15 identifies or could be used to identify a person shall be considered  
16 confidential information, subject to the provisions of section 5 of  
17 this act, and shall be treated as such by a semen bank, and shall not  
18 be subject to civil or administrative subpoena or discovery in a civil  
19 action, including, but not limited to, a judicial, administrative,  
20 arbitration, or mediation proceeding.
- 21       e. A person who reports information to the registry or acts on  
22 information obtained from the registry in good faith, or otherwise  
23 takes any action, in accordance with the provisions of this act and  
24 the rules and regulations adopted pursuant thereto, shall be immune  
25 from any civil or criminal liability that might otherwise be incurred  
26 or imposed with respect to those actions.
- 27
- 28       7. a. The commissioner shall be authorized to enter and inspect  
29 any semen bank and to make such investigation of the premises and  
30 the books and records as is reasonably necessary to carry out the  
31 provisions of this act.
- 32       b. It shall be a violation of this act for any person to obstruct,  
33 hinder, delay, or interfere, by force or otherwise, with the  
34 performance by the commissioner of any duty under the provisions  
35 of this act.
- 36       c. If the commissioner has reason to believe that a condition  
37 exists or has occurred at a semen bank, in violation of the  
38 provisions of this act, which is dangerous to the public health, the  
39 commissioner may order that semen bank to correct the violation  
40 and may suspend the license of the semen bank until the correction  
41 is completed. If a licensee denies that a violation exists or has  
42 occurred, the licensee shall have the right to apply to the  
43 commissioner for a hearing, in which case the hearing shall be held  
44 and a decision rendered within 72 hours of the receipt of the  
45 licensee's request. If the commissioner rules against the licensee,  
46 the licensee shall have the right to apply to the Superior Court for  
47 injunctive relief against the commissioner's order.

1 d. A person who violates the provisions of this act or an order  
2 of the commissioner shall be liable for the first offense to a civil  
3 penalty, to be established by the commissioner, of not less than  
4 \$100 nor more than \$1,000, and for the second and each succeeding  
5 offense for a civil penalty of not less than \$500 nor more than  
6 \$5,000. For the purposes of this subsection, each violation shall  
7 constitute a separate offense. The civil penalty shall be collected in  
8 a summary proceeding, brought in the name of the State in a court  
9 of competent jurisdiction pursuant to the "Penalty Enforcement Law  
10 of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

11  
12 8. A person, other than a semen bank licensed pursuant to  
13 section 3 of P.L. , c. (C. ) (pending before the Legislature as  
14 this bill), who sells, offers for sale, or otherwise transfers or seeks  
15 to transfer for valuable consideration, human semen, is guilty of a  
16 crime of the third degree except that, notwithstanding the provisions  
17 of N.J.S.2C:43-3 or any other law, a fine of up to \$50,000 may be  
18 imposed on the person.

19  
20 9. The Commissioner of Health, pursuant to the  
21 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et  
22 seq.), shall adopt rules and regulations to effectuate the purposes of  
23 this act.

24  
25 10. This act shall take effect on the first day of the seventh  
26 month next following the date of enactment, but the Commissioner  
27 of Health may take such anticipatory administrative action in  
28 advance thereof as shall be necessary for the implementation of this  
29 act.

## 30 31 32 STATEMENT

33  
34 This bill provides for the regulation of semen banks and semen  
35 donation in New Jersey.

36 The bill provides specifically as follows:

- 37 • A person is not to operate or conduct a semen bank in this State  
38 unless licensed by the Commissioner of Health under the  
39 provisions of the bill.
- 40 • The commissioner is to charge a fee for each license or its  
41 renewal in an amount determined by the commissioner to be  
42 reasonably necessary to cover the cost to the Department of  
43 Health of carrying out the provisions of the bill, but the fee may  
44 vary based on the number of collections made by a facility.
- 45 • A license is to be issued to any person who has been conducting a  
46 semen bank prior to the effective date of the bill upon submission  
47 of a properly completed application on a form and in a manner  
48 prescribed by the commissioner, including documentation to the

- 1 satisfaction of the commissioner that the semen bank is accredited  
2 by the American Association of Tissue Banks and is in  
3 compliance with federal regulations, and payment of the  
4 application fee.
- 5 • The commissioner, before refusing to grant a license, or before  
6 suspending or revoking a license previously granted, except as  
7 hereinafter provided in the bill, is to: give notice to the applicant  
8 or licensee personally, or by mail addressed to that person at the  
9 person's last known address; and afford that person an  
10 opportunity to be heard with respect thereto at a time and place  
11 specified in the notice.
  - 12 • A license issued in accordance with the provisions of the bill may  
13 be suspended or revoked by the commissioner for a violation of  
14 any of the provisions of the bill or any rules or regulations  
15 adopted pursuant thereto.
  - 16 • A licensee is not to collect semen without having first obtained  
17 the following from the prospective donor, on a form and in a  
18 manner prescribed by the commissioner:
    - 19 -- a completed registration statement which sets forth the name  
20 and address of the donor and contains such other information as  
21 prescribed by regulation of the commissioner or required pursuant  
22 to federal regulations; and
    - 23 -- a donor information sharing statement as set forth in the bill.
  - 24 • The commissioner is to establish standards of operation for semen  
25 banks, including standards for the collection, processing, storage,  
26 and distribution of semen, in consultation with the American  
27 Association of Tissue Banks and the American Society for  
28 Reproductive Medicine, and may incorporate by reference the  
29 requirements or guidelines adopted by those entities, as well as  
30 federal regulations, in the standards adopted pursuant to the bill.
  - 31 • The commissioner is to impose a limit on semen donations by an  
32 individual donor in accordance with recommendations of the  
33 American Society for Reproductive Medicine.
  - 34 • A semen bank is to report the information contained in the  
35 completed registration statement that it obtains for each donor to  
36 the New Jersey Semen Donor Registry established under the bill,  
37 and to check with the registry prior to obtaining each donation of  
38 semen from any donor.
  - 39 • The donor information sharing statement, required pursuant to the  
40 bill, is to specify the level of information that is to be shared with  
41 an individual 18 years of age or older if that individual submits a  
42 written, notarized request to obtain information pursuant to the  
43 bill. The donor may, in the future, ask to update and submit a  
44 revised statement to the semen bank, which is to report this  
45 information to the New Jersey Semen Donor Registry.
  - 46 • The donor information sharing statement is to specify the  
47 following options, from which the donor may select one:



- 1       -- "Complete information sharing" means a donor consents to the  
2 release of the donor's name, last known address, and telephone  
3 number, if available;
- 4       -- "Intermediary information sharing only" means a donor does  
5 not consent to the release of the above information, but agrees to  
6 communication with the individual requesting the information  
7 through a third party designated by the donor on the original or  
8 revised statement;
- 9       -- "Medical information sharing only" means a donor does not  
10 consent to the release of the above information, but agrees to  
11 periodic communication limited to the sharing of non-identifying  
12 family medical history information, with the individual requesting  
13 the information through a third party designated by the donor on the  
14 original or revised statement.
- 15       • The licensee is to maintain a copy of the completed and any  
16 revised donor information sharing statement.
- 17       • An individual who is 18 years of age or older may submit to the  
18 registry a written, notarized request for information about the  
19 person whom the individual has reason to believe was a donor.
- 20       -- If the donor submitted a donor information sharing statement  
21 specifying "complete information sharing," the registry is to provide  
22 that donor information to the requester.
- 23       -- If the donor submitted a donor information sharing statement  
24 specifying "intermediary information sharing only," the registry is  
25 to inform the requester of the donor's wish to communicate with the  
26 requester through the third party designated by the donor on the  
27 donor information sharing statement.
- 28       -- If the donor submitted a donor information sharing statement  
29 specifying "medical information sharing only," the registry is to  
30 inform the requester of the donor's wish for periodic  
31 communication limited to the sharing of non-identifying family  
32 medical history information with the requester through a third party  
33 designated by the donor on the donor information sharing statement.
- 34       -- If the donor submits a revised statement to the semen bank that  
35 is reported to the registry pursuant to the bill, the registry is to share  
36 information with the requester based on the revised statement in  
37 accordance with the provisions of the bill.
- 38       • The commissioner is to establish and operate a Statewide registry,  
39 to be designated as the New Jersey Semen Donor Registry, which  
40 shall be the repository for information obtained from semen  
41 banks pursuant to the bill.
- 42       -- The commissioner is to adopt regulations for the  
43 implementation, operation, and evaluation of the registry, including,  
44 but not limited to, regulations that prescribe the manner for a semen  
45 bank to submit information to, and obtain information from, the  
46 registry, and establish procedures to ensure the accuracy and  
47 confidentiality of information submitted to the registry.

- 1       -- The commissioner may contract with a public or private entity  
2 to implement or operate the registry.
- 3       -- All information collected or developed by the registry that  
4 identifies or could be used to identify a person is to be considered  
5 confidential information, subject to the provisions of the bill, and is  
6 to be treated as such by a semen bank, and not be subject to civil or  
7 administrative subpoena or discovery in a civil action, including,  
8 but not limited to, a judicial, administrative, arbitration, or  
9 mediation proceeding.
- 10      -- A person who reports information to the registry or acts on  
11 information obtained from the registry in good faith, and in  
12 accordance with the provisions of the bill and the rules and  
13 regulations adopted pursuant thereto, is immune from any civil or  
14 criminal liability that might otherwise be incurred or imposed with  
15 respect to those actions.
- 16      • The commissioner is authorized to enter and inspect any semen  
17 bank and to make such investigation of the premises and the  
18 books and records as is reasonably necessary to carry out the  
19 provisions of the bill.
  - 20      • If the commissioner has reason to believe that a condition exists  
21 or has occurred at a semen bank, in violation of the provisions of  
22 the bill, which is dangerous to the public health, the  
23 commissioner may order that semen bank to correct the violation  
24 and may suspend the license of the semen bank until the  
25 correction is completed. The licensee may apply to the  
26 commissioner for a hearing to contest the suspension, and the  
27 hearing will be held and a decision rendered within 72 hours of  
28 the receipt of the licensee's request. If the commissioner rules  
29 against the licensee, the licensee may apply for injunctive relief  
30 against the commissioner's order.
  - 31      • A person who violates the provisions of the bill or an order of the  
32 commissioner is liable for the first offense to a civil penalty, to be  
33 established by the commissioner, of not less than \$100 nor more  
34 than \$1,000, and for the second and each succeeding offense for a  
35 civil penalty of not less than \$500 nor more than \$5,000, which is  
36 to be collected in a summary proceeding, brought in the name of  
37 the State in a court of competent jurisdiction pursuant to the  
38 "Penalty Enforcement Law of 1999."
  - 39      • A person, other than a semen bank licensed pursuant to this bill,  
40 who sells, offers for sale, or otherwise transfers or seeks to  
41 transfer for valuable consideration, human semen, is guilty of a  
42 crime of the third degree and, notwithstanding the provisions of  
43 N.J.S.2C:43-3 or any other law, a fine of up to \$50,000 may be  
44 imposed on the person.
  - 45      • The bill takes effect on the first day of the seventh month after  
46 enactment, but authorizes the commissioner to take administrative  
47 action in advance as necessary for its implementation.